KAYLA ROBINSON

REGULATORY OPERATIONS SPECIALIST

CONTACT

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Durham, NC

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SKILLS

- eCTD Publishing
- eCTD Validation
- Lorenz docuBridge
- Veeva Vault RIM
- Document Formatting
- ICH E3
- Adobe Acrobat
- Excel
- Attention to Detail

EDUCATION

Bachelor of Science

05/2023

North Carolina State University

Raleigh, NC

Biology

CERTIFICATES

Regulatory Affairs Certification (RAC-Drugs)

06/2026

Regulatory Affairs Professionals Society (RAPS)

SUMMARY

Regulatory operations specialist with 3 years of eCTD publishing and document formatting for pharmaceutical submissions, from IND amendments to NDA supplements. Publishes and validates 250+ sequences a year, manages Veeva Vault RIM records and brings close attention to detail to every gateway deadline.

EXPERIENCE

Regulatory Operations Specialist 04/2024 - Present

Triangle Park Therapeutics Durham, NC

Commercial-stage pharmaceutical company with 4 marketed products and 6 active INDs.

- Publish **250+** eCTD sequences a year in Lorenz docuBridge, from IND safety reports to NDA supplements.
- Run eCTD validation on every sequence before FDA gateway transmission, with zero technical rejections.
- Manage Veeva Vault RIM records for 4,000 documents, keeping metadata and approval dates current.
- Train 20 authors on templates, bookmarks and hyperlinks, cutting formatting rework by 40%.

Regulatory Document Specialist 06/2023 - 03/2024

Research Triangle Clinical Services Morrisville, NC

Contract research organization supporting 30 biotech sponsors.

- Formatted 300 clinical study reports, protocols and appendices to ICH E3 and sponsor templates.
- Checked 1,500+ hyperlinks and bookmarks a month in Adobe Acrobat for submission-ready PDFs.
- Tracked 60 document deliverables for 5 sponsors in an Excel status log.
- Converted 40 Word templates to submission-ready styles used by every sponsor team.